

## **Remarks**

### **I. Status of the Application and Claims**

As originally filed, the present application had a total of 18 claims. All of these except claims 1-8 were withdrawn as the result of a restriction requirement. The Examiner has pointed out that claim 5 was not included in the application and therefore renumbered the pending claims as 1-7. All of these have been cancelled herein and new claims 19-31 have been added.

### **II. The Amendments**

As mentioned above, new claims 19-31 have been introduced herein. Support for each of these claims may be found in the application as set forth in Table 1.

<b>New Claim</b>	<b>Support in Application</b>
claims 19, 20 and 31	original claim 1
claims 21-24	page 5, lines 4-11; see also Examples 3 and 4
claim 25	original claim 4
claim 26	page 9, line 33 - page 10, line 28; Example 3, page 18, line 15 – page 21, line 14
claim 27	page 10, line 28 - page 11, line 4; Example 4, page 21, lines 15-32
claims 28 and 29	page 4, line 19-22 of the specification
claim 30	page 4, lines 12-16 of the specification

The amendments described above do not add new matter to the application and their entry is therefore respectfully requested.

### **III. Claim Objections**

On page 2 of the Office Action, the Examiner objects to claims 6-8 because a claim numbered as “5” was not included in the original filing. Since all of the claims pending in the

application have now been cancelled and new claims have been introduced, Applicants respectfully submit that this objection has been overcome.

## **The Rejections**

### **I. Rejection of Claims Under 35 U.S.C. § 101, First Paragraph**

On pages 2 and 3 of the Office Action, the Examiner rejects all pending claims based upon the allegation that a specific and credible utility has not been disclosed for the claimed polynucleotides.

Applicants respectfully traverse this rejection.

The application clearly demonstrates that the claimed polynucleotides can be used to increase the fermentative production of lysine by bacteria.<sup>1</sup> The effectiveness of this approach is demonstrated in Example 5 and it can be seen in Table 1 on page 22 of the application that bacteria transformed with plasmids carrying sequences encoding ptsH produce more amino acid than bacteria transformed with vector alone. In the case, of claims 29-31, sequences are claimed that may serve as probes in making and identifying the recombinant bacteria

The function described above should clearly be sufficient to meet the utility requirements of patentability regardless of whether the ptsH gene has other functions or not. Thus, Applicants submit that the present rejection is in error and respectfully request that it be withdrawn.

### **II. Rejection of Claims Under 35 U.S.C. §112, First Paragraph**

On pages 3 and 4 of the Office Action, the Examiner rejects claims under 35 U.S.C. § 112, first paragraph. Rejections based upon the enablement requirement are set forth in item 7 and those based upon the written description requirement are set forth in item 8. Below, Applicants respond to each allegation.

**A. Response to Allegations in Item 7**

In item 7, the Examiner rejects claims based upon the allegation that they are not properly enabled. The rejection appears to be largely based upon the assertion that the claimed polynucleotides lack an established utility and that it would require undue experimentation for one of skill in the art to search for a function. The Examiner concludes that one of skill in the art would have to search through vast numbers of polynucleotides to identify those that are part of Applicants' claims.

Applicants respectfully traverse this rejection.

As discussed above, the polynucleotides claimed in the present application have a clear function that has been experimentally demonstrated in the present specification. Specifically, the polynucleotides increase amino acid synthesis when recombinantly introduced into *C. glutamicum*. Thus, contrary to the Examiner's allegations, one of skill in the art would not have to search for a function.

Applicants also respectfully submit that the Examiner is using an inappropriate standard for evaluating enablement. The relevant question is whether one of ordinary skill in the art can make and use every embodiment falling within the scope of Applicants' claims. Applicants submit that the Office Action does not provide any basis whatsoever for concluding that such a person would not be able to synthesize a polynucleotide with a sequence falling within the scope of the present claims. There is also no reason to believe that one of ordinary skill in the art would not be able to use standard laboratory methods to introduce such polynucleotides into a vector, transform bacteria with the vector, and then use the transformants to produce amino acids. Clear guidance for these operations are given in the present specification and the effectiveness of the procedure is demonstrated with experimental data. Thus, Applicants respectfully submit that the enablement requirement of patentability has been met.

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<sup>1</sup> The lysine itself can be used as an additive in a wide variety of foods and food supplements.

**B. Response to Allegations in Item 8**

In item 8, the Examiner rejects claims based upon the written description requirement of patentability. It is alleged that the claims encompass a wide variety of polynucleotides but that the specification only provides the sequence of SEQ ID NO:1. Thus, the Examiner concludes that one of ordinary skill in the art would not recognize Applicants as having possession of the claimed invention.

Applicants respectfully traverse this rejection.

First, it should be appreciated that the claims introduced herein are of considerably more restricted scope than those reviewed by the Examiner. The claims still, however, encompass polynucleotides based upon their encoding proteins with an amino acid sequence 70% identical to SEQ ID NO:2.

The Federal Circuit has held that claims directed to polynucleotides do not meet the written description requirement of patentability when they are open-ended, *e.g.*, when they are based solely upon function. For example, a claim solely directed to polynucleotides encoding a protein with the activity of ptsH would not be valid. However, the present claims have both structural and functional limitations.

Structurally, the claims are limited to polynucleotides encoding proteins that are either identical in sequence to SEQ ID NO:2 or which are at least 70% homologous. The claims therefore encompass a very large number of specific compounds but this does not mean that the written description requirement of patentability has not been met. For example, chemical claims are often directed to compounds defined by a core structure and many variable groups. They therefore encompass millions of compounds even though only a few of the compounds may be expressly disclosed in the application. In the present case, the homology requirement limits the number of compounds to a defined group, *i.e.*, the claims are not open-ended. Even though it would be impractical, one of ordinary skill in the art could, in principle, write down

every compound claimed. Thus, conceptually, Applicants were clearly in possession of the claimed invention at the time of filing.

Some of the compounds having 70% homology might not be operative, *i.e.*, they might not be able to enhance amino acid synthesis when recombinantly introduced into a bacterium. However, in order to eliminate the inoperative embodiments, Applicants have coupled the requirement for maintaining a high degree of homology with the functional requirement that promotion of amino acid synthesis be maintained.

In light of the above considerations, Applicants respectfully submit that the present claims meet the written description requirement of patentability. It is therefore respectfully requested that the Examiner's rejection based upon the written description requirement of patentability be withdrawn.

### **III. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

On pages 4 and 5 of the Office Action, claims are rejected under 35 U.S.C. §112, second paragraph. The Examiner alleges that the phrase "at least 70% identical to a polynucleotide coding for a polypeptide that contains the amino acid sequence of SEQ ID NO:2" is vague and indefinite because the specific nucleotide sequences are not known and not recited in the claim.

Applicants respectfully traverse this rejection.

The requirements of 35 U.S.C. §112, second paragraph, are met if a claim defines an invention sufficiently for one of ordinary skill in the art to determine whether any given subject matter falls within the scope of the claim. In the present case, one of ordinary skill in the art would need to be able to determine whether a given polynucleotide encodes a protein with an amino acid sequence at least 70% homologous to that of SEQ ID NO:2. The determination of homology between proteins and the translation of nucleotide sequences into encoded proteins is a trivial undertaking for one of ordinary skill in the art of molecular biology. Determining whether a protein having 70% homology to that of SEQ ID NO:2

maintains the ability to enhance bacterial amino acid synthesis requires nothing more than following the procedures set forth in the application, *i.e.*, incorporating the sequence into an appropriate vector, transforming *C. glutamicum* bacteria with the vectors, and then measuring the amount of amino acid produced during incubation. Applicants therefore respectfully submit that the present claims define Applicants' invention sufficiently for one of ordinary skill in the art to determine whether they encompass any given polynucleotide. The claims therefore meet the requirements of 35 U.S.C. §112, second paragraph.

The Examiner also rejects claims based upon four other phrases. These are: "preferably recombinant DNA which is capable of replication in coryneform bacteria;" "within the degeneracy region of the genetic code;" "which hybridizes with the sequence;" and "functionally neutral sense mutations." Since all of these phrases have been eliminated from the claims as presented herein, Applicants respectfully submit that the Examiner's rejections have been overcome.

#### **IV. Rejection of Claims Under 35 U.S.C. §102**

On pages 5 and 6 of the Office Action, the Examiner rejects claims based upon 35 U.S.C. §102. Claim 1 is rejected as anticipated by Zhu, *et al.* (accession number L22432). The Examiner argues that the reference teaches a polynucleotide sequence containing at least 15 consecutive nucleotides derived from SEQ ID NO:2. Since the amended claims introduced herein do not have a provision directed solely to fifteen consecutive bases within the amino acid sequence of SEQ ID NO:2, Applicants respectfully submit that the Examiner's rejection has now been obviated. This should be clear for claims 1-28. Claims 29 and 30 now include a functional limitation which helps to distinguish the prior art

The Examiner also rejects claim 4 as being anticipated by Oliver, *et al.* (accession number AL009204). It is alleged that the reference teaches a polynucleotide sequence that will hybridize to SEQ ID NO:1 under low stringency conditions. Since Applicants no longer claim polynucleotides based solely upon their hybridization behavior, it is respectfully submitted that the Examiner's rejection has been obviated. In the case of claim 30, it should

be noted that polynucleotides are required to encode a protein "having the enzymatic activity of component H of the phosphotransferase system."

### Conclusion

In light of the amendments and discussion above, Applicants submit that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (703) 905-2173.

Respectfully submitted,

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